

### **REMARKS**

Applicants would like to thank the Examiner for careful consideration of this application. Claims 1-15 are pending in the application. Claims 1-15 have been amended and Claims 4 and 5 include allowable subject matter. Support for the amendments and the new claims can be found in the specification as originally filed. No new matter has been added.

### **REJECTIONS UNDER 35 USC 112 1<sup>st</sup> paragraph**

Claims 1-3 and 7-15 stand rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement standard.

The Examiner alleges that Claim 1 is directed to any and all organic acids. Applicants respectfully disagree. Amended independent Claim 1 is directed specifically to "enantiomerically enriched organic acid". Enantiomerically enriched organic acids are defined on page 5, lines 3-9 of the specification, and an extensive list of enantiomerically enriched organic acids, which the Examiner concedes as "being enabling", is provided on page 3, lines 11-29 and page 4, lines 1-10.

Furthermore, the MPEP states in § 2164.01(b), that as long as the specification discloses at least one method for making and using the claimed invention that bares a reasonable correlation to the entire scope of the claim, than the enablement requirement is satisfied. Additionally MPEP § 2164.04 states that a specification that contains teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement unless there is reason to doubt the objective truth of the statements contained therein. Accordingly, the burden rests with the Examiner to explain why the truth and accuracy of any statements in the supporting disclosure are in doubt. The Applicants submit that a list of "enantiomerically enriched organic acids" is provided in the disclosure that is enabling. For the reasons stated above, Applicants respectfully submit that the specification is enabling and respectfully request this rejection be

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withdrawn.

Rejections under 35 USC 112, 2<sup>nd</sup> Paragraph

Claims 1-9 and 11-15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1-9 and 11-16 stand rejected for not using proper claim language. In view of the above amendments, the Examiner's rejections have been attended to.

Furthermore, the Examiner states that the scope of Claim 1 is "completely unascertainable" in the absence of reaction conditions. Applicants disagree. Amended independent Claim 1 is directed to a process in which an enantiomerically enriched organic acid is reacted with one racemate of a racemic mixture. The racemates are separated and the enantiomerically enriched organic acid is separated away from the reacted racemate. Applicants submit that reaction conditions vary depending on the enantiomerically enriched organic acid used, and that the conditions necessary to initiate the racemate enantiomerically enriched organic acid can be determined by a skilled artisan without undue experimentation. Reconsideration is respectfully requested.

Claim 3 stands rejected because the Examiner alleges that more than the menthol derivative per se is being embraced. Applicants find the Examiner's rejection unclear. Menthol and menthol derivatives are well known in the art as are menthol isomers and stereoisomers. Furthermore, Applicants are unclear as to the relevance of the formula provided by the Examiner as information regarding chirality or constitutional isomers is not provided.

Claim 3 further stands rejected as the Examiner alleges that "N-protected amino acid" appears to include all amino acids and Claims 3 and 6 stand rejected as the Examiner alleges that the nature of the protected amino group is not clear since applicants do not indicate which amino acid needs to be protected. Applicants submit that the amino acids of Claim 3 are limited to "N-protected amino acids", and examples

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of N-protected amino acids are provided on page 3, lines 28 and 29 and page 4, lines 1-3 of the specification. Applicants respectfully submit that N-protected amino acids are well known in the art as being amino acids that have a protecting group, such as for example, Boc or tert-butyl bound at the  $\alpha$ -nitrogen. Again Applicants point to the examples of N-protected amino-acids provided on page 3, lines 28 and 29 and page 4, lines 1-3.

Claim 7 stands rejected as the Examiner alleges it is not clear what the decomposition temperatures of the reactants are. Applicants submit that the reaction temperature varies based on the decomposition temperature of the reactants since a variety of reactants may be used in the process of amended independent Claim 1. Furthermore, one skilled in the art would know the decomposition temperature of the specific reactant being used in the present claimed process and understand from the limitation provided in dependent Claim 7 that the reaction may not take place at a temperature above the decomposition temperature.

Claim 9 stands rejected as the Examiner appears to allege that 0.1-1 equivalent of any organic acid applicable. Amended dependent Claim 9 reads to the racemic 3-aminopentanenitrile being 0.1–1 equivalent of the enantomerically enriched organic acid.

Claims 10 and 11 stand rejected as the Examiner appears to allege that specific bases and acids, respectively, should be provided. Applicants respectfully disagree. The bases of amended dependent Claim 10 are limited to those that are stronger than the amine function of the of the 3- aminopentane nitrile, and the acids of amended dependent Claim 11 are limited to those acids that are stronger than the entomerically enriched organic acid. One skilled in the art would understand that the strength of an acid or base can be determined based on the  $pK_a$  value of the specific base or acid, and this depends on the type of the base or acid used. Furthermore, Applicants provide examples of bases and acids on page 7, lines 17-22 and page 8, lines 1-7, respectively.

In view of the amendments and remarks made herein above, Applicants

respectfully request reconsideration and withdrawal of the rejections of Claims 1-15 is respectfully requested.

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**REJECTIONS UNDER 35 U.S.C. 102(b)**

Claims 1-2 and 7-13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Williams et al., J. Nat. Prod. 2002, 65, 29-31 (hereinafter "Williams").

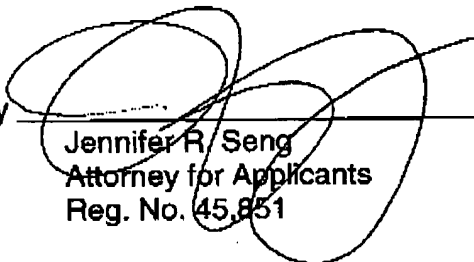
It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See *Motorola Inc. v. Interdigital Technology Corp.* 43 USPQ2d 1481 (1997 CAFC).

Williams fails to teach or suggest a "process for obtaining enantiomerically enriched 3-aminopentanenitrile" as recited in amended independent Claim 1. Rather, Williams describes a method for the synthesis of (R)-3-aminopentanenitrile from (R)-2-aminobutanol via a chemical multistep synthesis, and fails to address the separation of racemates after the synthesis. Therefore, Williams fails to teach or suggest any of the steps in the process of enantiomerically enriching 3-aminopentanitrile. Accordingly, Williams fails to anticipate amended independent Claim 1 and reconsideration of the rejection of amended independent Claim 1 is requested.

Claims 2 and 7-13, either directly or indirectly, depend from and add further limitations to amended independent Claim 1, and are deemed allowable for at least the same reasons in combination with amended independent Claim 1.

In view of the above amendments, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them

Respectfully submitted,

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